Efficacy of botulinum toxins on bruxism: an evidence-based review

CRD summary
The authors concluded that botulinum toxin injections can reduce the frequency of daytime and night-time parafunctional activity (bruxism) events, decrease bruxism-induced pain and satisfy patients’ self-assessment of the effectiveness on bruxism. Given potential for bias in the review, generally low quality included studies and the limited evidence presented, the authors’ conclusions may not be reliable.

Authors' objectives
To assess the efficacy of botulinum toxins on daytime or night-time parafunctional activity (bruxism).

Searching
Six electronic sources (including EMBASE and Cochrane CENTRAL) were searched from 1990 to April 2011 without language restrictions. Search strategies were reported.

Study selection
Eligible for inclusion in the review were randomised controlled trials (RCTs) or non-RCTs. Trials had to compare the efficacy of botulinum toxin injections versus an alternative intervention or placebo on bruxism. Eligible participants were adults over the age of 18 years. The primary outcome was the decrease in frequency of bruxism events. Secondary outcomes included decrease in pain scores and subjective evaluation of efficacy and improvements in sleep quality. Adverse events were reported in the review. Studies in which bruxism was caused by an underlying disorder (such as brain injury and medications) and studies that focused on treatments for other diseases were excluded from the review.

Studies administered 30 to 80 units of botox/dysport into the masseter muscles in the jaw line. One RCT also administered 20 units of botox into each anterior temporalis. Control groups in the RCTs received saline. One before-and-after study compared botox to night-time oral splints. Objective measures were used to detect bruxism. Different subjective measurement tools were used to assess pain levels and patient evaluations on the efficacy of botulinum toxins.

The authors did not state how many reviewers screened studies for inclusion.

Assessment of study quality
Studies were assessed for risk of bias based on Cochrane methods with criteria on randomisation and allocation concealment, blinding, reporting on incomplete outcome data, selective outcome reporting and other risk of bias.

The authors did not state how many reviewers performed the quality assessment.

Data extraction
Means and standard deviations were extracted for primary and secondary outcomes to calculate mean differences (MD) and their 95% mean differences (CI). The number of adverse events was extracted.

The authors did not state how many reviewers extracted outcome data.

Methods of synthesis
A random-effects model was used to combine mean differences and their 95% mean differences, where possible. Other results (including adverse events) were reported narratively.

Results of the review
Two RCTs (32 participants) and two controlled before-and-after studies (25 participants) were included in the review. Follow-up ranged from one week to six months. One RCT and one controlled before-and-after study did not adequately meet any of the quality criteria. The remaining RCT and controlled before-and-after study met two or four quality criteria.
**Bruxism frequency:** Bruxism events were statistically significantly reduced in patients who received botulinum toxins compared to saline at four (MD -3.54, 95% CI -4.68 to -2.40; one RCT), eight (MD -2.79, 95% CI -3.92 to -1.66) and 12 weeks (MD -2.70, 95% CI -3.92 to -1.66) after botulinum toxin injections detected using electromyogram (EMG).

Both RCTs reported on subjective evaluations of the effectiveness of botulinum toxins on bruxism. One RCT reported that subjective assessment of efficacy was significantly higher in the botulinum toxin group compared to saline group at six months after injection. Subjective differences did not differ between the two groups at any other follow-up time.

**Pain:** One RCT (20 participants) reported that botulinum toxins significantly reduced pain on chewing at six-month follow-up compared to saline placebo (p<0.05). No other findings in the RCT were significant.

One before-and-after study reported significant improvements in pain levels after botulinum toxin injections at one and three months (p<0.05).

The second before-and-after study reported that there were no significant differences in pain levels between patients who received botulinum toxins or used nocturnal oral splints.

Two studies reported that there were no adverse effects post-injection. None of the studies reported on sleep quality.

**Authors’ conclusions**
Botulinum toxin injections can reduce the frequency of bruxism events, decrease bruxism-induced pain levels and satisfy patients’ self-assessment of the effectiveness on bruxism.

**CRD commentary**
The review question and supporting inclusion criteria were clearly stated. There was a comprehensive search of the literature without language or publication restrictions (thereby minimising potential for missed data). Study quality was assessed using appropriate criteria and indicated that the studies were of unclear or low quality. It was unclear whether each stage of the review process was undertaken in duplicate which meant that reviewer error and bias could not be ruled out.

There appeared to be differences across the studies in terms of study design, treatment regimens and outcome measurement tools. Data on outcomes was generally limited.

Given the potential for bias in the review, the generally low quality of the studies and the limited evidence presented, the authors’ conclusions and recommendations for practice seem overly strong and may not be reliable.

**Implications of the review for practice and research**
**Practice:** The authors stated that botulinum toxin injections at a dosage below 100 units of the masseter or temporalis muscles were safe for otherwise healthy patients.

**Research:** The authors stated a need for further research (preferably RCTs of high quality) to investigate the effects of botulinum toxin injections on sleep quality improvement and compare the effects of botulinum toxins versus nocturnal oral splint on bruxism.

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